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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/464,528 12/15/99 FALCO

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EXAMINER

COLLINS, C

ART UNIT

PAPER NUMBER

1638

DATE MAILED:

01/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/464,528	FALCO ET AL.
Examiner	Art Unit	
Cynthia Collins	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 15 December 1999.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). _____
16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 20) Other: _____

DETAILED ACTION

Oath/Declaration

1. A foreign priority date is not claimed.

Claim Objections

2. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 2 is dependent on Claim 1 or Claim 10. Claim 10 is not a previous claim. Claim 10 is also drawn to a method of increasing or decreasing the expression of a heterologous nucleic acid fragment, rather than to a promoter. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

3. Claim 7 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claim has not been further treated on the merits.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is drawn to an isolated nucleic acid fragment comprising a constitutive plant SAMS promoter. However, the specification does not set forth what structural

or physical features are required in a constitutive plant SAMS promoter. The specification only discloses an isolated nucleic acid fragment (SEQ ID NO:6) comprising a constitutive soybean SAMS promoter. (Examples 4-7 pages 19-24).

6. That another plant SAMS promoter will function constitutively cannot be assumed merely on the basis of gene homology. Gomez-Gomez et al. teach that two homologous pea plant SAMS genes (the SAMS1 gene and the SAMS2 gene) exhibit different levels of expression and different patterns of tissue specific expression in peas (Plant Physiology, June 1998, Vol. 117, No. 2, pages 397-405). One of ordinary skill in the art would recognize that the level and pattern of expression for a gene is controlled by the promoter of that gene. Because some plant SAMS promoters do not function constitutively, the identification of a constitutive plant SAMS promoter is not adequately described.

7. See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir. 1997), where it states:

"The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA ... Accordingly, the specification does not provide a written description of the invention ..."

8. Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed promoter, and given the high level of unpredictability in this art of identifying nucleic acid sequences that would function as constitutive promoters, one skilled in the art would not have been in possession of the claimed promoter at the time this application was filed.

9. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid fragment comprising a constitutive soybean SAMS promoter comprising SEQ ID NO: 6, does not reasonably provide enablement for an isolated nucleic acid fragment comprising a constitutive plant SAMS promoter. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The breadth of the claims is not commensurate in scope with the enabling support provided.

10. The claim is drawn to an isolated nucleic acid fragment comprising a constitutive plant SAMS promoter. However, in the instant disclosure, applicants teach only the isolation of a constitutive soybean SAMS promoter comprising SEQ ID NO:6 (Specification Example 4 pages 19-21). The specification does not provide any definitive guidance for how to obtain other constitutive plant SAMS promoters, such as using a known plant SAMS gene as a heterologous probe to identify a genomic clone containing the promoter for a SAMS gene from a plant species other than soybean. Applicants also teach only the use of a constitutive soybean SAMS promoter comprising SEQ ID NO:6 (Examples 5-7 pages 21-24). The specification does not provide any definitive evidence that other plant SAMS promoters will function constitutively, such as transformation of a plant with a construct containing a reporter gene under the transcriptional control of another plant SAMS promoter. Furthermore, the specification does not set forth any specific structural or physical characteristics that would define constitutive promoter function, such as the identification of specific nucleotides whose alteration affects promoter activity.

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11. Guidance for making and using the claimed invention is necessary for enablement because promoters from different plant SAMS genes may not function constitutively (Gomez-Gomez et al., discussed *supra*).

12. Guidance for making and using the claimed invention is also necessary for enablement because even minor changes in the length or sequence of a promoter can alter both the level of activity as well as the tissue specificity of the promoter. Benfey et al. teach that the tissue specificities of subdomains of the CaMV 35S promoter can vary depending on the location of a subdomain within a promoter (Science, 1990, Vol. 250, pages 959-966). Individual promoter subdomains exhibited different patterns of tissue specific expression when used alone, as compared to when used in combination with a different subdomain. (Figure 1, page 960). Also, particular combinations of subdomains exhibited different patterns of tissue specific expression when transformed into different species of plants (Figure 4, page 963). In addition, different combinations of subdomains of the CaMV 35S promoter exhibited different levels of promoter activity (Table 1, page 963). Kim et al. teach that various point mutations in the *nos* promoter can alter the level of promoter activity in tobacco (Plant Molecular Biology, 1994, Vol. 24, pages 105-117). Mutation of one or more nucleotides in either of two hexamer motifs significantly decreased the level of *nos* promoter activity (Table 2, page 109). Thus, DNA sequence similarity is not always predictive of functional similarity for promoters.

13. Because other plant SAMS promoters may not function constitutively, and because other plant SAMS promoters would differ in length and/or nucleotide sequence as compared to a soybean SAMS promoter comprising SEQ ID NO:6, the claimed invention is not enabled by the specification in the absence of further guidance or example.

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14. Given the unpredictability of isolating a constitutive plant SAMS promoter, the absence of guidance in the specification for making and using such a promoter, the lack of any other working examples, and given the breadth of the claims which encompass any constitutive plant SAMS promoter, it would require undue experimentation by one skilled in the art to make and/or use the claimed invention.

15. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

16. Claims 1 and 8, and dependent claims 2-7 and 9-11, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

17. Regarding claim 1, and claims dependent thereon, the phrase "consists essentially of" renders the claim indefinite because it is not known what changes would or would not materially affect the basic and novel characteristics of the claimed nucleotide sequences.

18. Regarding claim 8, and claims dependent thereon, the phrases "increasing or decreasing the expression of at least one heterologous nucleic acid fragment" and "wherein the expression of the heterologous nucleic acid fragment is increased or decreased" render the claim indefinite.

The "at least one heterologous nucleic acid fragment" is operatively linked to a promoter.

Because a promoter *promotes* the transcription of the nucleic acid sequence to which it is operatively linked, the phrases "increasing or decreasing the expression of at least one heterologous nucleic acid fragment" and "wherein the expression of the heterologous nucleic acid fragment is increased or decreased" are indefinite and confusing, since it is unclear how the expression of the heterologous nucleic acid fragment could decrease under the control of said promoter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell can be reached on (703) 308-4310. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and 1 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Cynthia Collins
January 26, 2001

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600

Elizabeth McElwain